Advice on NIH SBIR & STTR Grant Applications – Timeline

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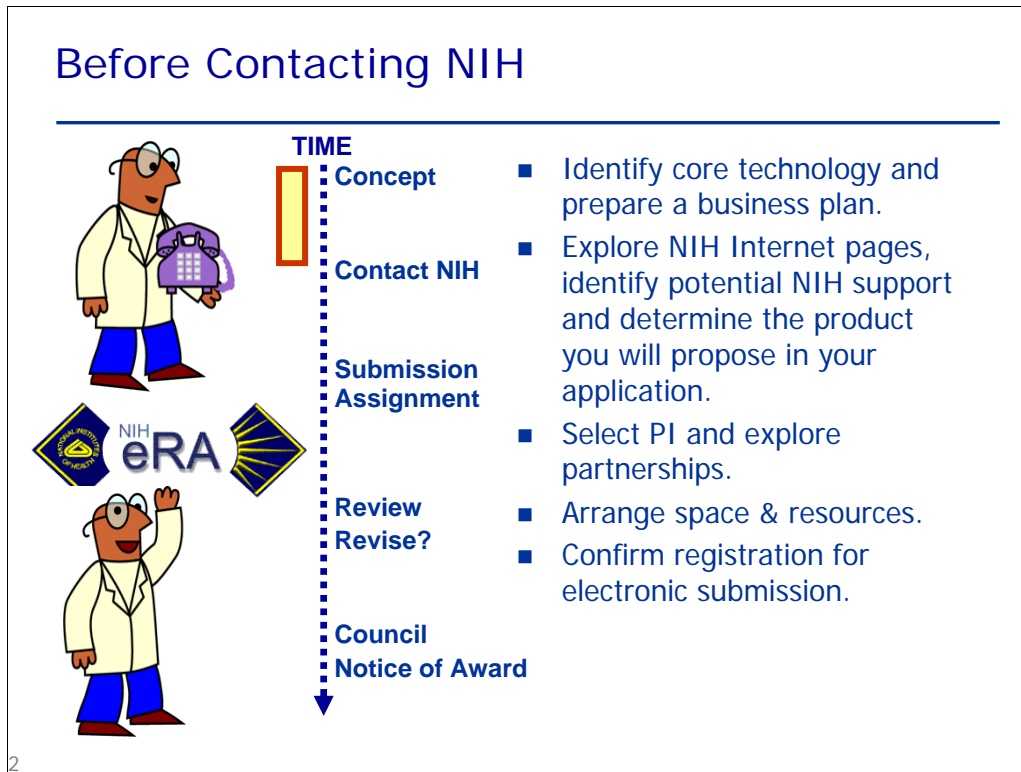National Institute of Allergy and Infectious Diseases

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Hello, I am Gregory Milman and in this presentation I provide advice on who you should contact at NIH and when you should contact them. This presentation was updated in June 2006. Send your comments, suggestions, and criticisms to gmilman@niaid.nih.gov.

Before Contacting NIH

TIME

Concept

Contact NIH

Submission Assignment

NIH eRA

Review Revise?

Council Notice of Award

- Identify core technology and prepare a business plan.
- Explore NIH Internet pages, identify potential NIH support and determine the product you will propose in your application.
- Select PI and explore partnerships.
- Arrange space & resources.
- Confirm registration for electronic submission.

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On the left is a timeline that runs from your development of a concept for NIH small business funding to our issuing a Notice of Grant Award.

A yellow rectangle illustrates where we are in the process.
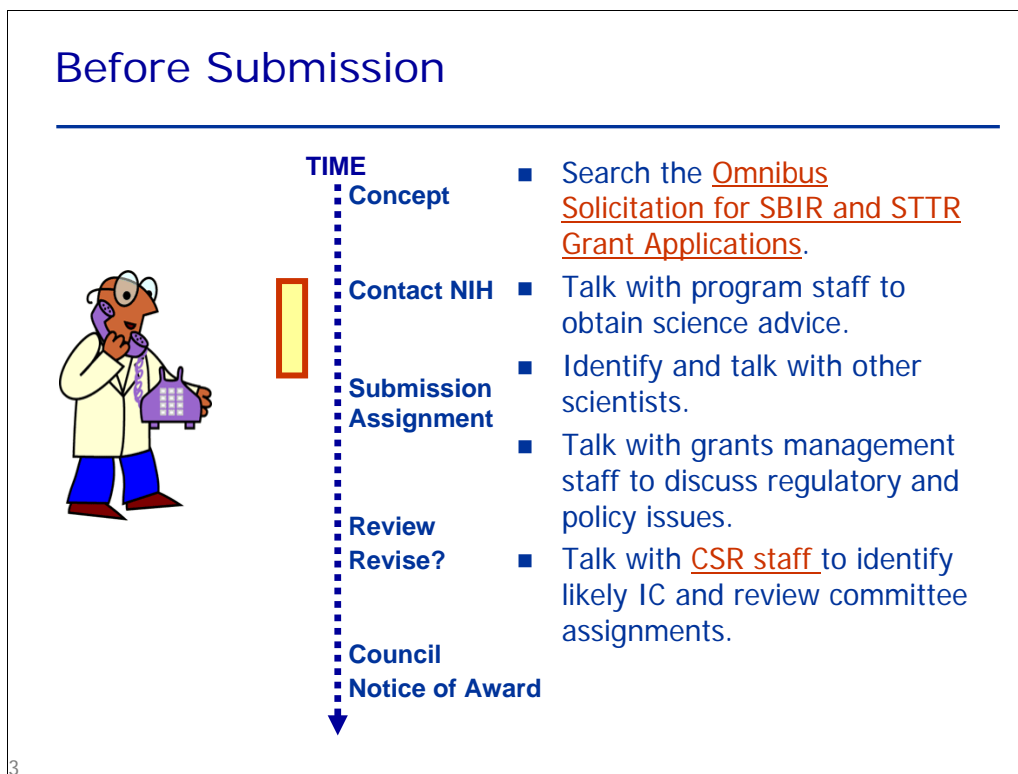
Do your homework before calling NIH.

Identify your core technology and prepare a business plan.

Explore the NIH Internet pages and decide on your likely NIH product and your likely NIH source of support.

Select a Principal Investigator, explore strategic partnerships, and arrange for space and resources.

Confirm that your company is registered both with Grants.gov and the eRA Commons, and that the PI is registered and associated with your company in the Commons.

Now you are ready to contact NIH staff.

Before Submission

TIME

Concept

- Search the Omnibus Solicitation for SBIR and STTR Grant Applications.

Contact NIH

- Talk with program staff to obtain science advice.

Submission Assignment

- Identify and talk with other scientists.

- Talk with grants management staff to discuss regulatory and policy issues.

Review Revise?

- Talk with CSR staff to identify likely IC and review committee assignments.

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Notice of Award

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Search the Omnibus Solicitation for SBIR and STTR topics to identify IC programs, research topics, and contact staff most appropriate for your proposal. Early in the planning stages of your application, you will want to obtain science advice from program staff. The more knowledgeable you are, the more productive your conversation is likely to be. You may learn that your technology is more relevant to a different program or funding component.

Ask who you could contact both in and outside NIH to get additional information on your proposed research. Bounce your ideas off as many scientists as possible. Refine your ideas and proposal based on your conversations.

If there are regulatory or policy issues that may affect your application, you should begin conversations with grants management staff.

You could also start communications with the Center for Scientific Review staff to identify the IC likely to be assigned your application, and the review committee likely to be assigned your proposal.

Program Staff

- Discuss the state-of-the-art, research trends, gaps and roadblocks.
- Identify your competition.
- Identify resources to help you.
- Identify other funding opportunities.
- Provide informal and sometimes more blunt feedback from the review.
- Be your advocate in the process.

Ask program staff to help you better understand the state-of-the-art in your research area. Talk about research trends, gaps and roadblocks, and your competition.

Also, ask program staff to identify resources you might use and other funding opportunities.

Although they do not participate in the review process, program staff often attend application review meetings.

When they do, they can provide you with informal and sometimes more blunt feedback from the review than you will read in the summary statement.

If a program staff person believes in the value of your proposal, she or he may be your advocate for funding if your application is on the waitlist I described previously.

Grants Management Staff

- Administrative matters.
- Budget.
- Rules and regulations.
- Policy issues.

You will mainly interact with grants management staff during and after preparation of a Notice of Grant Award. However, you may want to talk with them before submitting an application if you have questions on administrative matters. These include budgets outside the normal levels, rules and regulations, and policy issues on human subjects and vertebrate animals.

Learn About Your Review Committee

- **CSR Review Staff**.
- **Information on review assignment**.
- **Pub Med Central**.
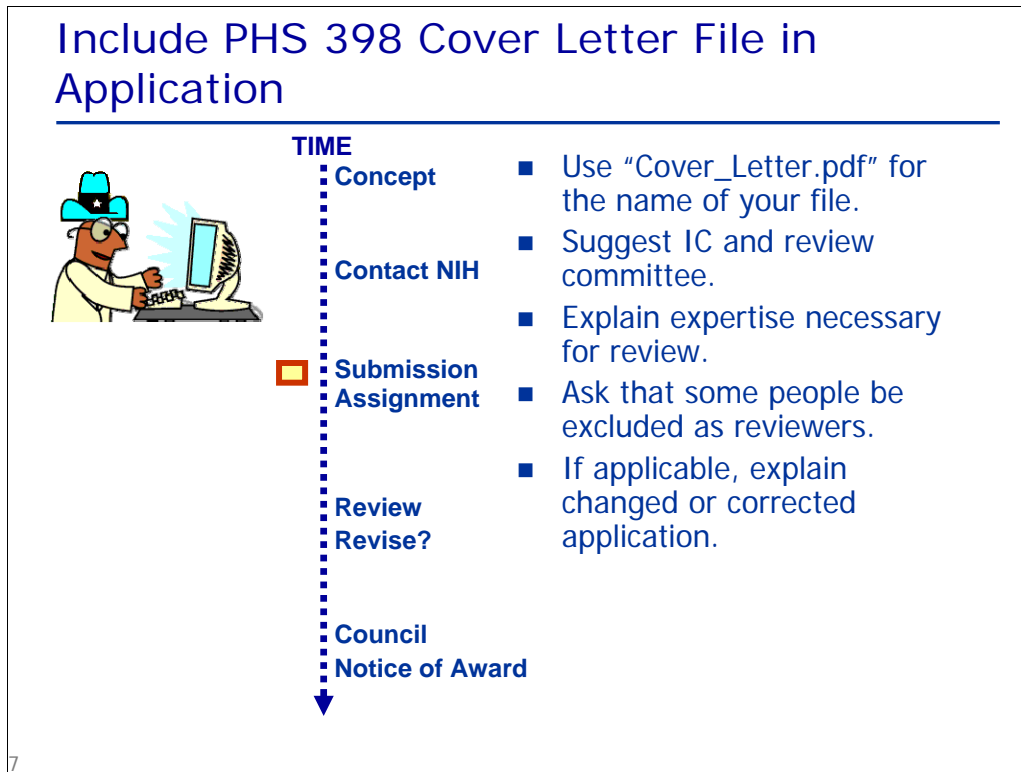- **CRISP - Computer Retrieval of Information on Scientific Projects**.

Many applicants for NIH grants make the big mistake of believing they should please the NIH institute or center to which their application will be assigned. Instead, I suggest you think of your review committee as the "primary customer" for your application.

I suggest you learn as much as possible about your reviewers. Before you send NIH your application, communicate with CSR staff to identify which review committee manager, known as a scientific review administrator or SRA, and which review group is likely to receive it. Examine the CSR website for rosters of review groups. Many of these same reviewers may be on the review group for your application.
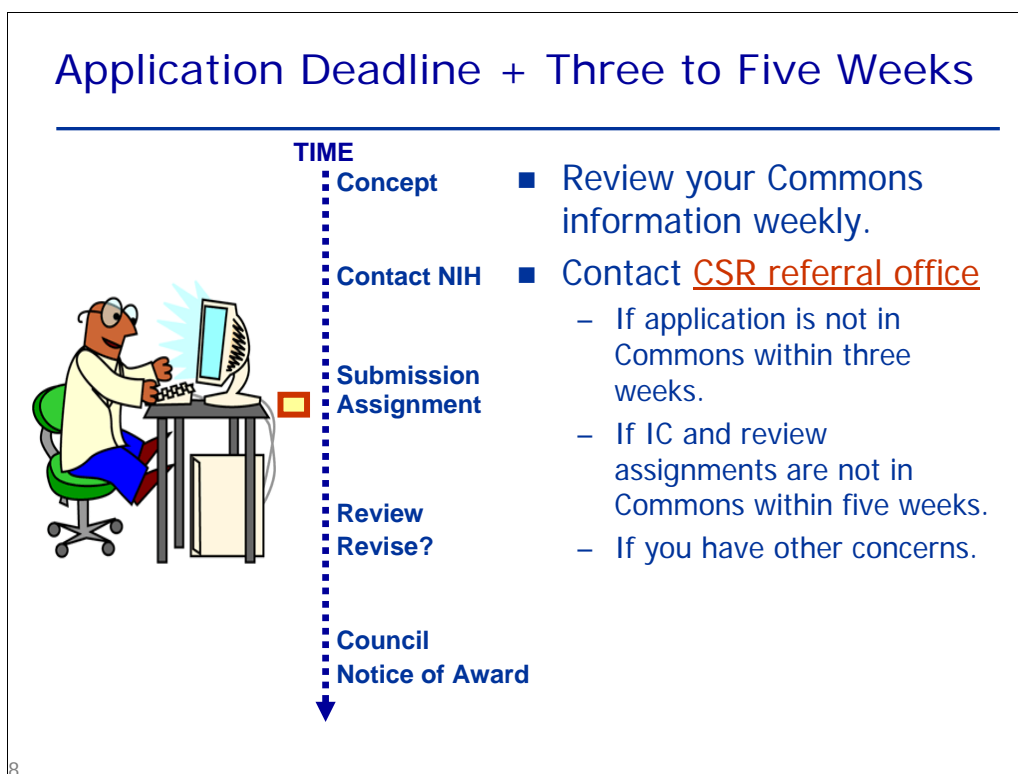
I encourage you to conduct a literature search on potential reviewers to learn their areas of expertise. Pay particular attention to the publications of those reviewers likely to receive primary assignment of your application. You can use the National Library of Medicine's Pub Med Central site to search for publications by author.

I also encourage you to use the NIH CRISP database. CRISP stands for Computer Retrieval of Information on Scientific Projects. You can search CRISP to learn if potential reviewers have NIH funded projects and read abstracts of their proposals. Be particularly cautious if the hypotheses in your application differs from ones they espouse.

Include PHS 398 Cover Letter File in Application

TIME

Concept
- Use "Cover_Letter.pdf" for the name of your file.

Contact NIH
- Suggest IC and review committee.
- Explain expertise necessary for review.

Submission
Assignment
- Ask that some people be excluded as reviewers.
- If applicable, explain changed or corrected application.

Review
Revise?
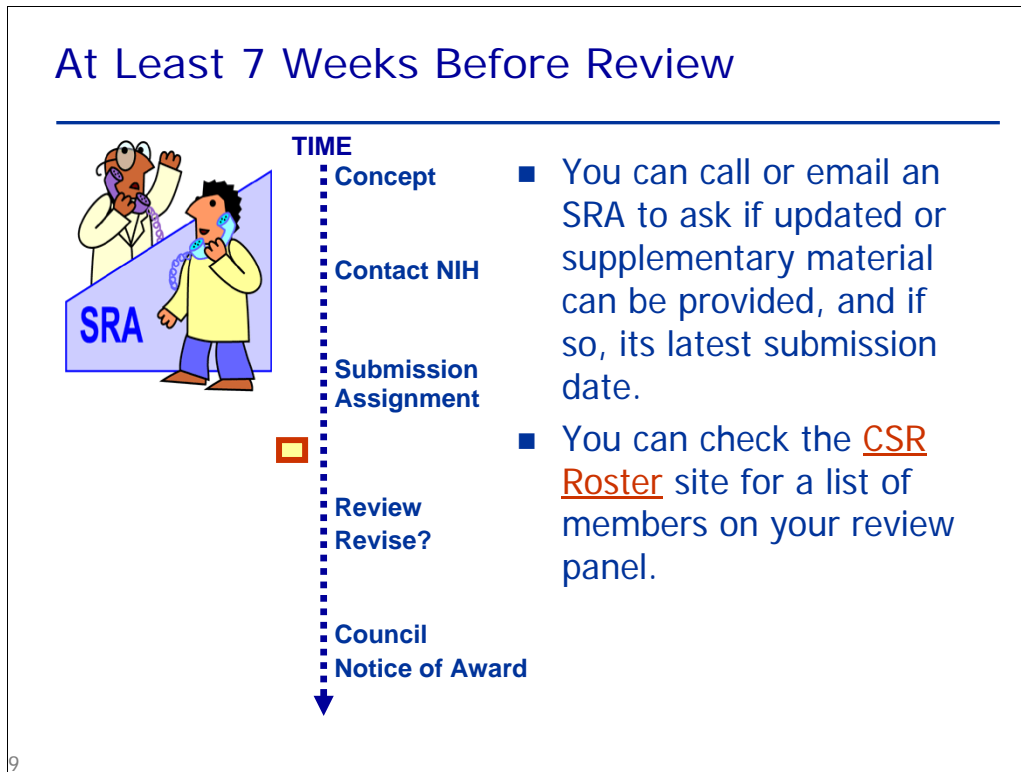
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When you submit your application, include a PDF-formatted PHS 398 Cover Letter File located under optional documents on the main PureEdge page. I suggest you name the file Cover_Letter.pdf and include the following information:

- Title of your application.

- Title of PA or RFA if appropriate.

- Suggested assignment to an IC and review committee with your reasons.

- Disciplines and expertise required to review your proposal.

- List of people (e.g., competitors) who should not review your application and why. Be careful though! If you exclude too many reviewers, your application may be placed in a panel with little expertise in your scientific area. Never suggest reviewers for your application.

- If your application is changed or corrected, explain why and include all the information from your previous cover letter.

Application Deadline + Three to Five Weeks

TIME

Concept

Contact NIH

Submission
Assignment

Review
Revise?

Council
Notice of Award

- Review your Commons information weekly.
- Contact <u>CSR referral office</u>
  - If application is not in Commons within three weeks.
  - If IC and review assignments are not in Commons within five weeks.
  - If you have other concerns.

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Within fifteen working days after the electronic receipt deadline, your application should be assigned a grant number by CSR. Within five weeks of the receipt date, the Commons should show an assignment to a review panel, the date the panel meets, the primary assignment to an NIH IC, and your assigned IC program staff.

If your application is not assigned a grant number within fifteen working days, or if other assignment information does not appear within five weeks, contact the CSR referral office, preferably by email so you have a communication record. Also, contact the CSR referral office if you have concerns about your application's IC or review panel assignment.

At Least 7 Weeks Before Review

TIME
Concept

Contact NIH

Submission
Assignment

Review
Revise?

Council
Notice of Award

SRA

- You can call or email an SRA to ask if updated or supplementary material can be provided, and if so, its latest submission date.
- You can check the CSR Roster site for a list of members on your review panel.

There is a limited window after submission, up to seven weeks before review, when you may be able to provide additional information or correct or update some information in your application. If you discover such a need, don't wait – contact the SRA as early as possible with your request.

Also, check the CSR Internet site to see who will be on your application's review panel. This is the time for you to request the exclusion of specific reviewers but you will have to provide good reasons for their exclusion. Be aware that the SRA is under no obligation to agree to any of your requests.

Special Emphasis Panels (SEP) Composition

- Approximately 75% of reviewers are the same from one review meeting to the next.
- Many members also serve on standing Integrated Review Groups (IRG).
- Some members ad-hoc with special expertise in science or business.
- Center for Scientific Review (CSR)
  - Review guidelines
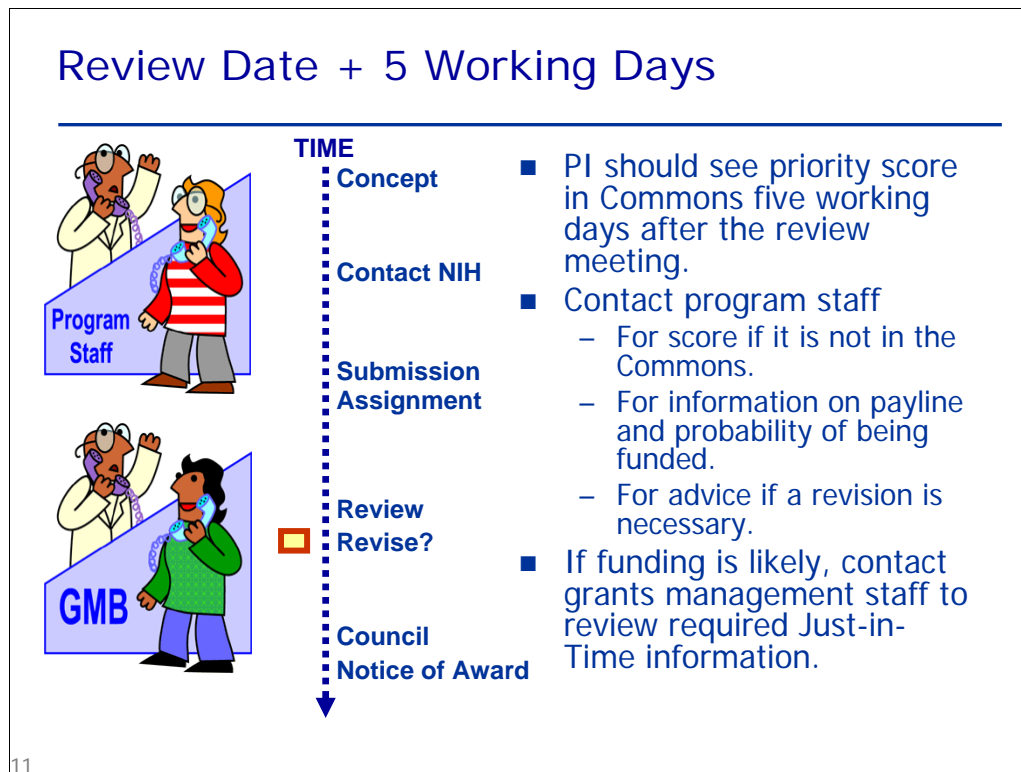 - SBIR/STTR Study Sections
  - Meeting dates

Although SBIR/STTR special emphasis panels called SEPs, may have different reviewers for each review meeting, approximately 75% of the panel members remain constant.

Many of the SEP members also serve on standing Integrated Review Groups, known as IRGs.

Others may have special expertise in a science or business area for that particular set of applications.

The Center for Scientific Review Internet site provides SBIR/STTR review guidelines, a list of current review committees and their SRA managers, and dates for upcoming review meetings.

Review Date + 5 Working Days

TIME
- Concept
- Contact NIH
- Submission
- Assignment
- Review
- Revise?
- Council
- Notice of Award

Program Staff

GMB

- PI should see priority score in Commons five working days after the review meeting.
- Contact program staff
  - For score if it is not in the Commons.
  - For information on payline and probability of being funded.
  - For advice if a revision is necessary.
- If funding is likely, contact grants management staff to review required Just-in-Time information.

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A priority score should appear in the PI's Commons account within five working days after the review meeting. Be aware that the score is not available to the Signing Official. If your score has not appeared within five working days, you can call or email your program staff listed in the Commons to identify the delay.

Ask your program staff about the current payline and the probability of your application being funded.

If you are told that your application is not likely to be funded, ask for advice on preparing a revised application even though a summary statement will probably not appear in the Commons for another five to seven weeks.

If you are told that you are likely to be funded, contact your grants management staff listed in the Commons to review the Just-in-Time information that you will need to provide before we issue an award.

Advice for Applications on the Waitlist

WAITLIST

SBIR

- Program staff is your best source of information about your assigned IC. Ask:
  - Will the IC award rate be similar to FY2005?
  - Does the IC fund applications in priority order or by IC priorities?
  - If by IC priorities, will your program staff be a champion for your application?
  - If your STTR application will not be funded, can it be transferred to another IC for funding?
- If you submitted for the April or August receipt dates, consider revising and resubmitting by the next receipt date for funding in the same fiscal year.
- If you are going to wait for end-of-year funding, complete your Just-in-Time information for grants management.
- If your SBIR priority score is over 200, seriously consider revising your application to respond to reviewer suggestions.
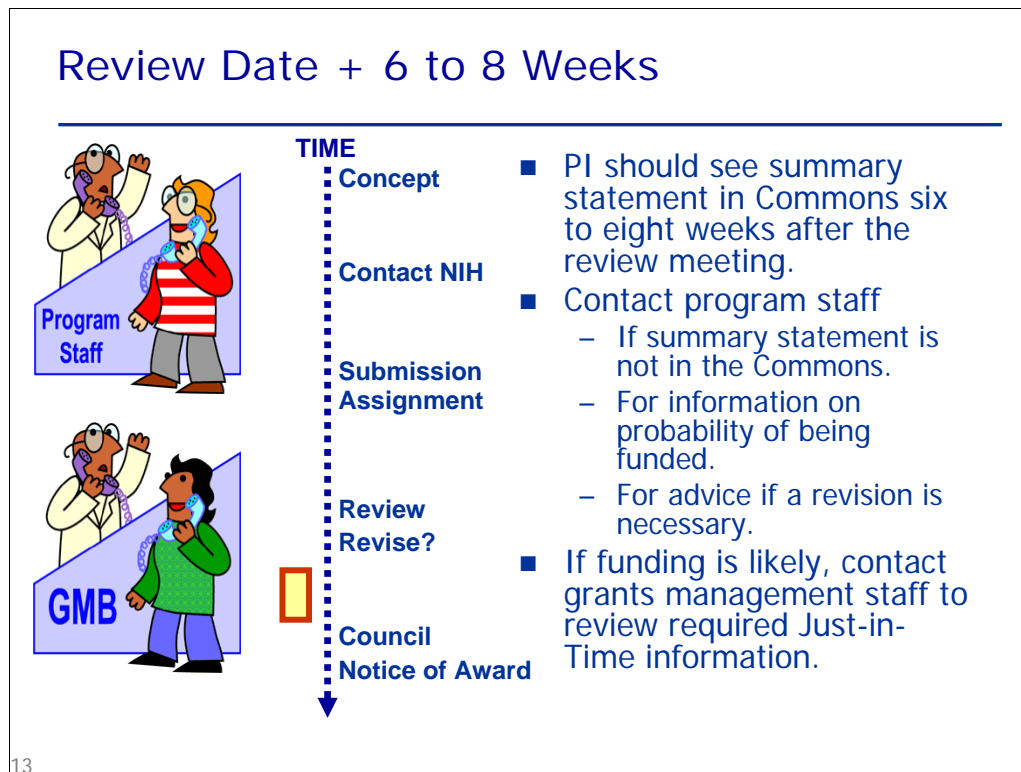
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Program staff is your best source of information about your assigned IC. Ask:

- Will the IC award rate be similar to FY2005?

- Does the IC fund applications in priority order or by IC priorities?

- If the IC selects by priorities, will your program staff champion payment of your application?

- If your STTR application will not be funded, can it be transferred to another IC for funding?

If you submitted for the April or August receipt dates, consider revising and resubmitting by the next receipt date for funding in the same fiscal year.

If you are going to wait for end-of-year funding, complete your Just-in-Time information for Grants Management.

If your priority score is over 200, seriously consider revising your application to respond to reviewer suggestions.

Review Date + 6 to 8 Weeks

TIME

Concept

Contact NIH

Submission
Assignment

Review
Revise?

Council
Notice of Award

Program Staff

GMB

- PI should see summary statement in Commons six to eight weeks after the review meeting.
- Contact program staff
  - If summary statement is not in the Commons.
  - For information on probability of being funded.
  - For advice if a revision is necessary.
- If funding is likely, contact grants management staff to review required Just-in-Time information.

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Your summary statement should appear in the Commons within six to eight weeks following the review meeting.

If your summary statement has not appeared in the Commons after eight weeks, contact your program staff listed in the Commons to inquire about the delay.

Again, inquire about the probability of funding and discuss revising your application if funding is unlikely.

If funding is likely, you should contact Grants Management Staff to review the Just-in-Time information that you will need to provide before NIH issues an award.
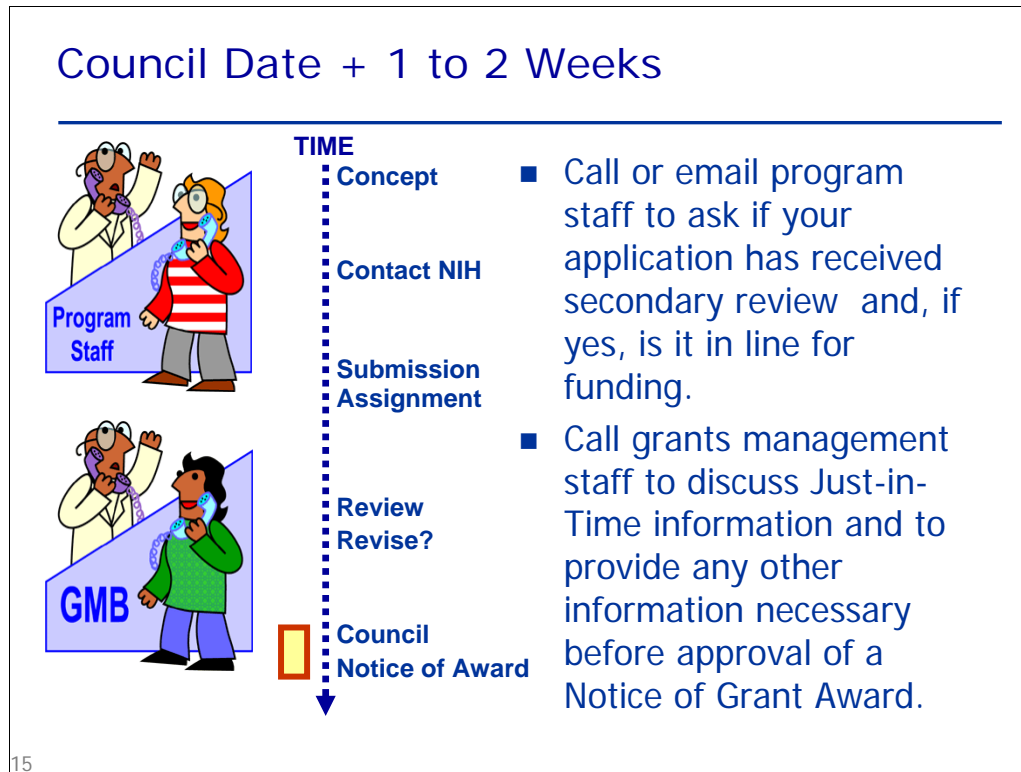
Common Reasons for Poor Priority Scores

- Lack of new or original ideas.
- Absence of an acceptable scientific rationale.
- Lack of experience in the essential methodology.
- Questionable reasoning in experimental approach.
- Diffuse, superficial, or unfocused research plan.
- Lack of sufficient experimental detail.
- Lack of knowledge of published relevant work.
- Unrealistically large amount of work.
- Uncertainty concerning future directions.

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If any of these common reasons for poor priority scores appears in reviewers' comments, you need to rethink, reorganize, and rewrite your application.

- Lack of new or original ideas.

- Absence of an acceptable scientific rationale.

- Lack of experience in the essential methodology.

- Questionable reasoning in experimental approach.

- Diffuse, superficial, or unfocused research plan.

- Lack of sufficient experimental detail.

- Lack of knowledge of published relevant work.

- Unrealistically large amount of work.

- Uncertainty concerning future directions.

Council Date + 1 to 2 Weeks

TIME
- **Concept**
- **Contact NIH**
- **Submission Assignment**
- **Review**
- **Revise?**
- **Council**
- **Notice of Award**

Program Staff

GMB

- Call or email program staff to ask if your application has received secondary review and, if yes, is it in line for funding.
- Call grants management staff to discuss Just-in-Time information and to provide any other information necessary before approval of a Notice of Grant Award.

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Although you should have a pretty good idea if your application is in line to be funded based on its priority score and your communication with program staff, there are additional gates your application must pass through before receiving an award.

Call your program staff to learn if your application has received secondary review and if it is slated for funding.

Grants management staff must verify that you meet all the requirements for funding. This gate is the one where many SBIR or STTR applications are delayed or blocked. If you haven't been contacted by grants management staff, this may be your fate too.

Call your grants management staff to confirm that you meet all requirements for funding and ask when you can expect a Notice of Grant Award.

More Presentations

TOPICS

- Basics
- Choices and FY2005 Data
- Grantsmanship
- Electronic Application
- NIH Timeline

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Thank you for watching this presentation. Close this window to select another topic.